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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,898	DECKERS ET AL.	
	Examiner	Art Unit	
	Yong D. Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-18 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-18 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a CIP of 09/577,147, now issued as U.S. Patent No. 6,372,234.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 1, 2005, amending claim 14, has been entered.

Claims 14-18 and 29 are pending and are under consideration.

Response to Arguments

Applicant's amendment and arguments filed on December 1, 2005, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and claims 15-18 and 29 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the phrase "substantially intact oil bodies". It is not clear to the Examiner either from the specification or form the claims as to what applicants mean by "intact bodies". As applicants have not provided a definition for the above phrase, the metes and bounds of the phrase in the context of the above claim are not clear to the Examiner. It is also not clear to the Examiner what is considered as "substantially intact" by the applicants. A perusal of the specification did not provide a clear definition for the above phrase. Without a clear definition, those skilled in the art would be unable to conclude if oil bodies are "substantially intact oil bodies" without knowing the metes and bounds of the phrase.

Further, It is unclear to the Examiner how "intact oil bodies" are prepared or how "intact oil bodies" are separated from non "intact oil bodies". In the context of the above, Examiner takes the position that these claims are incomplete for omitting essential steps, such omission amounting to a gap between the steps. The omitted steps are: steps in preparing only "intact oil bodies" or separating "intact oil bodies" from non "intact oil bodies".

In response to the previous Office Action, applicants have traversed the above rejection. Applicants argue that since the claims have been amended to recite "substantially intact oil bodies", the claims are no longer indefinite. Examiner respectfully disagrees. It is not clear to the Examiner what is considered as

"substantially intact" by the applicants. A perusal of the specification did not provide a clear definition for the above phrase. Without a clear definition, those skilled in the art would be unable to conclude as to which specific oil bodies are "substantially intact oil bodies" without knowing the metes and bounds of the phrase.

Hence the rejection is maintained.

Claims 14 and claims 15-18 and 29 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear to the Examiner how "intact oil bodies" are prepared or how "intact oil bodies" are separated from non "intact oil bodies". In the context of the above, Examiner takes the position that these claims are incomplete for omitting essential steps, such omission amounting to a gap between the steps. The omitted steps are: steps in preparing only "intact oil bodies" or separating "intact oil bodies" from non "intact oil bodies".

Applicants have not provided any arguments for the rejection. Therefore, the rejection is maintained.

Claim 14 and claims 15-18 and 29 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the phrases "capable of regulating transcription" and "capable of terminating transcription". A polynucleotide that is "capable" of carrying out a reaction conveys that the polynucleotide may have the same properties under all or other conditions. A polynucleotide "capable" of exhibiting a given activity may not have such property at all times or that such property is inherent to said polynucleotide. Therefore, it is not clear what are those conditions in which the polynucleotide phrases "capable of regulating transcription" and "capable of terminating transcription". Examiner requests clarification of the above phrase and suggests amending said phrase.

Claim 14 and claims 15-18 and 29 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the phrases "conditions to permit expression". Growing cell under "conditions that permit expression" of a polypeptide conveys that the polypeptides are not expressed under all conditions or that special conditions are required fro expression. Therefore, it is not clear what are those conditions in which the polypeptides is expressed. Examiner requests clarification of the above phrase and suggests amending said phrase.

Claim 14 and claims 15-18 and 29 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the phrase "sufficient portion to provide targeting to an oil body". The metes and bounds of the phrase in the context of the above claim are not clear to the Examiner. It is not clear to the Examiner what is considered as a "sufficient portion" by the applicants. It is also not clear to the Examiner what is "targeted" to the oil body. A perusal of the specification did not provide a clear definition for the above phrase. Without a clear definition, those skilled in the art would be unable to conclude oil body proteins having a "sufficient portion" without knowing the metes and bounds of the phrase or what is "targeted" to an oil body.

Claim 14 and claims 15-18 and 29 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the phrase "oil body protein". The metes and bounds of the phrase in the context of the above claim are not clear to the Examiner. The phrase is not common in the art. A perusal of the specification did not provide a clear definition for the above phrase. Therefore, it is not clear to the Examiner either from the specification or from the claim as to what proteins are encompassed by the phrase "oil body proteins". Examiner requests clarification of the above phrase.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-18 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14-18 and 29 are drawn to a method of preparing an emulsion formulation by isolating oil bodies comprising a fusion protein and washing said oil bodies to obtain a washed oil body preparation comprising "substantially intact oil bodies". However, washing said oil bodies isolated from cells to obtain an oil preparation comprising of "substantially intact oil bodies" were not described in the application as originally filed nor in any of its parent applications. The specification as filed only contains disclosure of obtaining "substantially intact oil bodies" from ground plant seeds. Obtaining "substantially intact oil bodies" derived from recombinant cells was not described. Therefore, claims 14-18 and 29 contain new matter.

Applicants in their remarks indicate that support for "intact oil bodies" can be found in the specification at page 6, lines 15-26 and original claim 14 and support for "substantially intact oil bodies" can be found in the specification at page12, lines 12-17. However, upon perusal of the specification at the above pages and claim 14, Examiner found no support for the amendments. Original Claim 14 (filed on July 15, 2001) has no recitation of the limitation "intact oil bodies". Page 6, lines 15-26 of the specification also does not define "intact oil bodies". Page12, lines 12-17 of the specification also does not define or recite washing oil bodies to obtain "substantially intact oil bodies".

The specification as filed only contains disclosure of obtaining "substantially intact oil bodies" from ground plant seeds.

Therefore, claims 14-18 and 29 contain new matter.

Given this lack of description of obtaining intact oil bodies from washing oil bodies derived from a recombinant cell, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 14-18 and 29 at the time of filing of the instant application.

Claims 14-18 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14-18 and 29 are drawn to a method of preparing an emulsion formulation comprising a fusion protein by transforming a plant host cell with a polynucleotide encoding a fusion protein comprising a sufficient portion of an oil body protein or oleosin and a thioredoxin or thioredoxin reductase. The claims encompass the use of any oil body proteins/oleosin and any thioredoxin/thioredoxin reductase, including recombinants, mutants and variants thereof. Therefore, the claims are drawn to a method of preparing an emulsion formulation by transforming a genus of any or all plant cells with a polynucleotide encoding a fusion protein comprising a genus of oil

body proteins/oleosins having any structure and a genus of thioredoxin/thioredoxin reductase having any structure. The specification only teaches a method of preparing an emulsion formulation comprising a fusion protein comprising a oleosin of SEQ ID NO:9 and thioredoxin reductase of SEQ ID NO:6 by transforming an Arabidopsis host cell with a polynucleotide encoding said fusion protein. This is not enough and does not constitute a representative number of species to describe the whole genus comprising polynucleotides encoding any or all oil body proteins or any or all oleosin and the whole genus comprising polynucleotides encoding any or all thioredoxin/thioredoxin reductase used to transform any plant host cells. There is no evidence on the record of the relationship between the structure of the oleosin of SEQ ID NO:9 and the structure of any or all oil body proteins or oleosins, including any or all recombinants, mutants and variants thereof. Similarly, there is no evidence on the record of the relationship between the structure of the thioredoxin reductase of SEQ ID NO:6 and the structure of any or all thioredoxin reductase, including any or all recombinants, mutants and variants thereof. There is also no evidence on the record of a method for successfully transforming and expressing proteins having full enzymatic activity in any or all plant host cells. Therefore, the specification fails to describe a representative species of the genus comprising polynucleotides encoding any or all oil body proteins or any or all oleosin, genus comprising polynucleotides encoding any or all thioredoxin or thioredoxin reductase and used to transform a genus comprising any or all plant host cells.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention

in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 14-18 and 29.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 14-18 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preparing an emulsion formulation comprising transforming an Arabidopsis host cell with a polynucleotide encoding a fusion protein fusion protein comprising an oleosin of SEQ ID NO:9 and thioredoxin reductase of SEQ ID NO:6, does not reasonably provide enablement for a method of preparing an emulsion formulation by transforming any or all plant cells with a polynucleotide encoding a fusion protein comprising an oil body protein/oleosin having any structure and thioredoxin/thioredoxin reductase having any structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4)

the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 14-18 and 29 are drawn to a method of preparing an emulsion formulation comprising a fusion protein by transforming any cell or any plant host cell with a polynucleotide encoding a fusion protein comprising a sufficient portion of any or all oil body protein or oleosin and a thioredoxin or thioredoxin reductase. The claims encompass the use of any oil body proteins/oleosin and any thioredoxin/thioredoxin reductase, including recombinants, mutants and variants thereof. Therefore, the claims are drawn to a method of preparing an emulsion formulation by transforming any or all plant cells with a polynucleotide encoding a fusion protein comprising an oil body protein/oleosin having any structure and thioredoxin/thioredoxin reductase having any structure. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the use of extremely large number of polynucleotides encoding oil body proteins/oleosins and thioredoxin/thioredoxin reductase, including variants, mutants and recombinants thereof, used to transform any plant host cells, broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins'

structure relates to its function. However, in this case the disclosure is limited to a method of preparing an emulsion formulation comprising a fusion protein comprising a oleosin of SEQ ID NO:9 and thioredoxin reductase of SEQ ID NO:6 by transforming an Arabidopsis host cell with a polynucleotide encoding said fusion protein. It would require undue experimentation of the skilled artisan to make and use the claimed variants and mutants of any oil body protein or oleosin, variants and mutants of any or all thioredoxin or thioredoxin reductase and any or all plant host cells. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polynucleotides and host cells encompassed by the method of these claims.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass a method of preparing an emulsion formulation by transforming any or all plant cells with a polynucleotide encoding a fusion protein comprising an oil body protein/oleosin having any structure and thioredoxin/thioredoxin reductase having any structure, because the specification does not establish: (A) regions of the proteins, oleosin and thioredoxin/thioredoxin reductase whose structure which may be modified without affecting its thioredoxin/thioredoxin reductase activity or use as an oil body protein; (B) the general tolerance of oil body proteins/oleosin and thioredoxin/thioredoxin reductase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue on these proteins with an expectation of obtaining the desired biological function; (D) a universal method of transforming and expressing said type of fusion protein with its full activity in any cell or any or all plant host cells; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the use of any or all oil body protein or oleosin, thioredoxin/thioredoxin reductase and any plant host cell to prepare an emulsion formulation comprising a fusion protein comprising said oil body protein and thioredoxin/thioredoxin reductase. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any or all oil body protein or oleosin,

thioredoxin/thioredoxin reductase, including variants, mutants and recombinants thereof, having the desired biological characteristics recited in the claim and transformation of any plant host cell is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-16, 18 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moloney et al., Wieles et al. and Owen et al.

Claims 14-16, 18 and 29 are drawn to a method of making an emulsion comprising a chimeric polynucleotide comprising a polynucleotide capable of regulating transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an oleosin obtained from plant seeds and a thioredoxin or thioredoxin reductase which is further linked to a polynucleotide capable of terminating transcription in a plant cell, wherein oil bodies comprising the fusion protein is isolated. Claim 29 limits claim 14 in that the thioredoxin or thioredoxin reductase of the emulsion reduces a target.

Moloney et al. (WO 96/21029 - form PTO-1449) discloses method of producing a fusion protein by introducing into a plant cell a chimeric polynucleotide comprising a polynucleotide capable of regulating transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an oleosin obtained from plant and a heterologous protein of interest which is further linked to a polynucleotide capable of terminating transcription in a plant cell, (pages 2-3). The method of Moloney et al. comprises growing said transformed plant host cell under conditions permitting expression of said fusion polypeptide, isolating oil bodies comprising said fusion polypeptide and washing said oil bodies comprised of intact oil bodies via centrifugation (pages 2-3 and 10-11). Centrifugation is given as an example of "washing oil bodies", page 12. Also, since it is not clear to the Examiner what is considered as "substantially intact oil bodies" by the applicants and since Moloney et al. also teaches that the enzyme of the fusion protein retains its enzymatic properties (page 21) indicating the

heterologous protein is intact, Examiner takes the position that the "washed oil body preparation" comprising the fusion protein of Monoloney et al. is "substantially intact".

The difference between the reference of et al. and the instant invention is that the reference of Moloney et al. does not teach a method of emulsifying the washed oil bodies comprising the fusion protein, wherein the heterologous protein is a thioredoxin or a thioredoxin reductase.

Polynucleotides encoding many thioredoxin and thioredoxin reductases are known in the art see NiceZyme: EC 1.8.1.9 – cited previously on form PTO-892). Wieles et al. (cited previously on form PTO-892) teaches polynucleotides encoding a thioredoxin and thioredoxin reductase (abstract and pages 921-922). Wieles et al. also teaches that thioredoxin and thioredoxin reductase are involved in redox regulation (abstract).

Owen et al. (US Patent 5,444,041 – form PTO-892) discloses a method of formulating emulsions comprising biologically active proteins (Column1-4). Owen et al. teaches many advantages of making such emulsions, such as prolonging shelf life of the protein (Column 3).

Therefore, combining the teachings of Moloney et al., Wieles et al. and Owen et al., it would have been obvious to one having ordinary skill in the art to modify the method of Moloney et al. by making a chimeric construct comprising a fusion protein wherein the heterologous protein is the thioredoxin or thioredoxin reductase of Wieles et al. and to further formulate the fusion protein into an emulsion. One of ordinary skill in the art would have been motivated to use thioredoxin or thioredoxin reductase as the

heterologous protein in the fusion protein of Moloney et al. since thioredoxin and thioredoxin reductases are important proteins in redox regulation. One of ordinary skill in the art would have been motivated to formulate a fusion protein into an emulsion to increase the shelf life of the thioredoxin or thioredoxin reductase. One of ordinary skill in the art would have had a reasonable expectation of success of making a fusion protein and isolating the fusion protein since Monoley et al. teaches that fusion proteins comprising oleosins and isolating said fusion protein. One of ordinary skill in the art would have had a reasonable expectation of success in making the emulsion since Owen et al. successfully teaches a method of making emulsions comprising biologically active proteins.

Therefore, the above references render claims 14-16, 18 and 29 *prima facie* obvious to one of ordinary skill in the art.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moloney et al., Wieles et al. and Owen et al. as applied to claims 14-16, 18 and 29 above, and further in view of Hildebrand et al.

Claim 17 is drawn to a method making an emulsion comprising a fusion protein, wherein the fusion protein is expressed in safflower cells.

The references of Moloney et al., Wieles et al. and Owen et al.combination teach a method of making an emulsion comprising a fusion protein comprising a thioreodixn or thioredoxin reductase and an oleosin, as discussed above.

The difference between the combined references and the instant invention is that the combined references do not teach the method using a safflower cell for the expression of the fusion protein.

Hildebrand et al. (EP 0 550 162 A1 – cited previously on form PTO-892) teach a method of expressing heterologous proteins in safflower cells (page 4).

Therefore, in combining the above references, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to express the fusion protein in safflower cells. The motivation of expressing the fusion protein in safflower cells is to express the oil body protein in an oil-bearing crop. One of ordinary skill in the art would have had a reasonable expectation of success since expression of fusion proteins in plant cells such as safflower cells are performed routinely in the art.

Therefore, the above references render claim 17 is *prima facie* obvious to one of ordinary skill in the art.

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652

Manjunath Rao
Primary Patent Examiner 1652